UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,547	01/26/2004	Seung-Hak Choi	YPL-0077	1634

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EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
11/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/08 has been entered.

Claims 1-14 are currently pending and under consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 12-14 are drawn to a method or installation for performing a genotyping analysis on a target sample. The method comprises receiving results of a biochip test, detecting a biochip identifier, selecting an analysis algorithm, downloading the algorithm, performing the genotyping analysis and storing results in a client system.

Since the claims are drawn to a method that involves judicial exception, the following analyses of facts of this particular patent application follows the rationales

suggested in the Office's guidance to examiners under the Memorandum "Clarification of

'processes' under 35 USC § 101" (published May 15, 2008, available online

www.uspto.gov/web/patents/memorandum.htm) and the "Interim Guidelines for

Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices:

22 November 2005, available from the US PTO website at

http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm), which is

incorporated in the MPEP 2106.IV.C.2.

Paragraph three of the Memorandum states:

*"Based on Supreme Court precedent[1] and recent Federal Circuit decisions, the
Office's guidance to examiners is that a § 101 process must (1) be tied to another
statutory class (such as a particular apparatus) or (2) transform underlying
subject matter (such as an article or materials) to a different state or thing.[2] If
neither of these requirements is met by the claim, the method is not a patent
eligible process under §101 and should be rejected as being directed to
nonstatutory subject matter."*

The methods of the instant claims are not tied to another statutory class (such as a

machine) either explicitly or inherently. Nominal or token recitations will not suffice,

e.g. displaying, inputting, obtaining, etc. See ex parte Langemyr; Appeal 2008-1495,

decided May 28, 2008. Reciting another statutory class in the preamble does not make

the invention tie to the statutory class. Furthermore, in the instant invention, there is no

physical transformation because a process of manipulating biochip data, at least for one

embodiment thereof, does not transform an article or physical subject to a different state

or thing. Therefore, at least one embodiment of the claimed method is not a statutory

process.

Additionally, the Guidelines states:

> *To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):*
>
> *- The claimed invention "transforms" an article or physical object to a different state or thing.*
>
> *- The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation for reasons set forth above, thus the Examiner then determines if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner determines each standard individually. For a claim to be "useful," the claim must produce a final result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete," the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the claim is rejected as non-statutory.

In the instant case, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. Since at least for one embodiment of the claimed invention, the process merely uses a mathematical model or algorithm to manipulate data without using or making available for use the results of the manipulation to enable its functionality and usefulness to be realized, it does not produce

a tangible result. While the result is stored in a system, it may not be available to a user to use. This could be mended by amending the claims to recite a step of outputting the final result to a user. However, applicant is cautioned against introducing new matter into the claims.

With regard to claims 1-11, drawn to a system or computer readable medium comprising instructions for performing the process of claims 12-14, since the process claims do not produce a useful, concrete and tangible result for reasons set forth above, the system and medium for performing the process do not produce a useful, concrete and tangible result and thus nonstatutory for the same reasons.

Furthermore, with regard to claims 9-11, drawn to computer readable medium, while the instant specification does not explicitly define the scope of the limitation of "computer readable medium," one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being "a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave." See column 14, claim 12. Bornstein et al., in US patent 6,1443,88 (Date of patent : Nov. 7, 2000) state, "The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave." See column 8, lines 33-37.

Therefore, at least one embodiment of the instant claims are drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical

characteristics of a form of energy, such as a frequency, voltage, or the strength of a

magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural

phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a

claim reciting a signal encoded with functional descriptive material, e.g. a computer

program, falls within any of the categories of patentable subject matter set forth in § 101.

The following analysis on why such a signal encoded with functional descriptive material

is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for

Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices:

22 November 2005, available from the US PTO website at

http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm):

First, a claimed signal is clearly not a "process" under § 101 because it is not a
series of steps. The other three § 101 classes of machine, compositions of matter and
manufactures "relate to structural entities and can be grouped as 'product' claims in
order to contrast them with process claims." 1 D. Chisum, Patents §1.02 (1994. The
three product classes have traditionally required physical structure or material.

"The term machine includes every mechanical device or combination of
mechanical device or combination of mechanical powers and devices to perform
some function and produce a certain effect or result." Corning v. Burden, 56 U.S.
(15 How.) 252, 267 (1854). A modern definition of machine would no doubt include
electronic devices which perform functions. Indeed, devices such as flip-flops and
computers are referred to in computer science as sequential machines. A claimed
signal has no physical structure, does not itself perform any useful, concrete and
tangible result and, thus, does not fit within the definition of a machine.

A "composition of matter" "covers all compositions of two or more substances
and includes all composite articles, whether they be results of chemical union, or of
mechanical mixture, or whether they be gases, fluids, powders or solids." Shell
Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C.
1957), aff'd, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not
matter, but a form of energy, and therefore is not a composition of matter.

> *The Supreme Court has read the term "manufacture" in accordance with its*
> *dictionary definition to mean 'the production of articles for use from raw or*
> *prepared materials by giving to these materials new forms, qualities, properties, or*
> *combinations, whether by hand-labor or by machinery." Diamond v. Chakrabarty,*
> *447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers,*
> *Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes*
> *the Century Dictionary). Other courts have applied similar definitions. See American*
> *Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied,*
> *220 U.S. 622 (1911). These definitions require physical substance, which a claimed*
> *signal does not have. Congress can be presumed to be aware of an administrative or*
> *judicial interpretation of a statute and to adopt that interpretation when it re-enacts*
> *a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus,*
> *Congress must be presumed to have been aware of the interpretation of manufacture*
> *in American Fruit Growers when it passed the 1952 Patent Act.*

> *A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3]*
> *(citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product*
> *is a tangible physical article or object, some form of matter, which a signal is not.*
> *That the other two product classes, machine and composition of matter, require*
> *physical matter is evidence that a manufacture was also intended to require physical*
> *matter. A signal, a form of energy, does not fall within either of the two definitions of*
> *manufacture. Thus, a signal does not fall within one of the four statutory classes of §*
> *101.*

> *[...]*

> *These interim guidelines propose that such signal claims are ineligible for patent*
> *protection because they do not fall within any of the four statutory classes of § 101.*
> *Public comment is sought for further evaluation of this question.*

Thus, claims 9-11 are drawn to nonstatutory subject matter.

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of
> making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the
> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall
> set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Independent claims 1, 9, and 12 are amended to recite "selecting an analysis algorithm relevant to the biochip identifier." Applicant points support for the limitation to page 6, line 16. A review of this section and other sections by the Office does not reveal adequate support for the new limitation in the specification. While it discloses selecting an algorithm, it does not disclose selecting an algorithm that is relevant to the biochip identifier. The new limitation is thus deemed new matter.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 9 and 12 are amended to recite selecting an analysis algorithm relevant to the biochip identifier. The metes and bounds of the limitation are unclear. It is not clear as to what "relevant" means in the context of the biochip identifier, whether it is relevant because it is used to create the identifier or it is used to recognize the identifier or the algorithm has other functions in relation to the identifier, such as performing a series of functions once the identifier is recognized, or else.

The other claims are rejected because they also contain the indefinite limitation.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by

Osborne et al. (IDS document: Artificial Intelligence System for Genetic Analysis, WO

01/16860 A2, March 8, 2001).

In view of the indefiniteness of the claims as set forth above, the art is being

applied to the best interpretation of the claims as written.

The claims are amended to be drawn to a server-client network system for

genotyping analysis on a target sample. The network comprises a server including an

analysis algorithm database for the genotyping analysis and a client system

communicatively coupled to the server, which receives the results of a biochip test on the

target sample, detects a biochip identifier, selects and downloads an analysis algorithm

relevant to the chip identifier, performs the genotyping analysis and stores the results in

the client system.

With regard to at least independent claims 1 and 12, Osborne et al. disclose a

network system and a method for genetic analysis. The network system comprises a

server that includes multiple databases required for the genetic analysis, which are

provided to client that receives the results of a microarray analysis and performs the

genetic analysis. See at least Fig. 1. and pages 4-5. The genetic analyses include analysis

of genomic mutations (see page 12, lines 30-31), which is interpreted as a type of

genotyping. Osborne et al. disclose that the system comprises central data processing

facilities and user facilities and that "each user facility may include an optical scanning

system to collect hybridization signals from a nucleic acid array, an image processing

system to convert the optical data into a set of hybridization parameters, a connection to a

data network, and a user interface to display, manipulate, search, and analyzed

hybridization information." See page 5. The system comprises various types of users at

different tiers including remote users/local users, web users/internet users, diagnostic

users including diagnostic master users, and browser users (see pages 10-12), any and all

of which is interpreted as being part of the client system as recited in the instant claims.

Since the user facilities (interpreted as client) and the central data processing facilities

(interpreted as server) comprising the databases are linked by encrypted network

connections (see page 5), it is interpreted that the databases in the server are provided to

the client and that the client system is communicatively coupled to the server.

Furthermore, Osborne et al. state on page 12:

There are two categories of diagnostic users, such as "diagnostic master users"
and "diagnostic users". Accounts for diagnostic master users are authorized and
correspond to the user sites where the systems are deployed. These diagnostic
master users are allowed to authorize accounts for diagnostic users. For clinical
applications, diagnostic users correspond to the individuals that have been tested.
For research and development applications, diagnostic master users can designate
either individual chip test results or groups of chips as a single diagnostic user,
wherein this option lies with the diagnostic master users in order to meet their
testing and analysis needs. Diagnosis processing is a key part of the artificial
intelligence system. The diagnosis processing for clinical applications may be
different from that of research and development applications. Diagnosis
processing for clinical applications implements a rules based analysis application
which utilizes a database set of rules and results. Diagnosis processing thereby

determines which conditions apply to the various combinations of gene expression levels and personal medical history.

The accounts authorized to diagnostic users are also interpreted as part of the client system as the accounts correspond to the user sites. Additionally, this statement clearly indicates that for a diagnostic user, i.e. client, to perform the diagnosis processing, the user first receives the systems because they "are deployed," and the system includes databases of rules, etc., which are interpreted as analysis algorithms.

With regard to claims 2 and 13, the databases in the server disclosed by Osborne include database for chip ID and pattern/lay-out, analysis algorithm and a quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for analysis in the system. Because the algorithm is for analysis of the biochip data and the biochip has identifier, it is interpreted as the algorithm is relevant to the biochip identifier in view of the indefiniteness of the limitation set forth above.

With regard to claims 3-4, the server of the system by Osborne et al. comprises database that is built up from statistical data for the results of test on a number of patients and references samples using microarrays. Osborne et al. disclose that the database server stores hybridization profiles, patient profiles, reference information, clinical information associated with hybridization profiles, and statistical summaries. See page 5. Osborne et al. further disclose that "hybridization profiles collected by remote and/or local facilities include clinical observations or other information associated with each profile, and the profile with associated observations is added to the central database." See page 6. Osborne et al. also state that "the databases of the instant invention continually mature and develop into more and more complex systems as information from public and private

sources continues to be added to the existing database." See pages 13 and 15. Thus, the databases are being built up while the users use the system.

With regard to claim 5, in the system disclosed by Osborne et al., the users/clients comprise optical scanning system and identifier recognizer. See at least Fig. 1 and pages 11 and 16.

With regard to claims 6-8 and 14, which include limitations that the client comprises an engine for performing a series of logical functions, in the system disclosed by Osborne et al., the client comprises an engine or means for performing a function of detecting the identifier of the biochip (see Fig. 1 and the "application ID on at least page 16, array ID and array location ID on at least pages 26-27, and sample ID, patient ID, etc. on pages 28-29). Client can select and download data/database based on application ID, etc., and perform genotyping analysis. See the diagnostic architecture listed on pages 16-18. Furthermore, with regard to claim 8, the method of Osborne et al. allows client to perform the genetic analysis including reading results via scanning system, (see pages 16-18), linking results with spot position information of the chip, etc. (see pages 13-14, where the database queries include chip ID genetic pattern, pattern match, result output, etc. and page 15). Users can perform functions such as correlating they hybridization signals of one or more probes and creating test hypothesis relating to a particular pathological or physiological condition, using the server databases to search, correlate, manipulate and display existing data, etc. See page 15.

With regard to claims 9-11, which are drawn to computer readable medium comprising computer executable instructions for executing the method steps and functions performed by the system above, given that the system for performing the functions and method steps as set forth above is a web-based computer systems including server and client, it would be readily recognized by one skilled in the art that the system

inherently comprises computer readable medium containing computer executable

instructions for performing the functions.

Applicant's arguments filed 10/22/08 have been fully considered but they are not

found persuasive.

Applicant lists a plurality of things that Osborne discloses or teaches and what the

instant specification discloses, but does not particularly point exactly what in the instant

claims are not disclosed in Osborne. With regard to the newly added limitation to the

claims that an algorithm relevant to the biochip identifier is selected for analysis, it is

addressed in the above section of rejection under 35 USC 102 in the context and in view

of the indefiniteness of the limitation set forth above in the section of rejection under 35

USC 112, second paragraph. Applicant appears to argue that Osborne does not disclose a

database storing chip IDs, layouts of the chips, etc. See page 11 of 12 of the response.

This is not found persuasive because first of all, these limitations of chip layout etc. are

not required in at least claims 1, 9 and 12. Further, the limitation have been address in the

previous Office action and reiterated above. The databases in the server disclosed by

Osborne include database for chip ID and pattern/lay-out, analysis algorithm and a

quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also

pages 19-22 for rules/algorithm for analysis in the system. Because the algorithm is for

analysis of the biochip data and the biochip has identifier, it is interpreted as the

algorithm is relevant to the biochip identifier in view of the indefiniteness of the

limitation set forth above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER